

**REMARKS**

In the interest of compact prosecution, Applicant hereby amends independent claim 1 to incorporate features found in dependent claim 9 and accordingly cancels claim 9. As such, claims 1, 5, 6, 8 and 10 are all the claims pending in the present Application.

Further, claim 10 has been amended to delete the recitations of isradipine and glipizide.

Accordingly, no new matter has been introduced by these amendments to the claim, and it is believed that they do not raise any issue that requires further search or consideration. Therefore, entry of the amendment and allowance of the application are respectfully requested.

**I. Preliminary Matter**

Applicants thank the Examiner for acknowledging the claim for foreign priority in the Office Action of March 15, 2007.

However, it appears that the Examiner inadvertently has not acknowledged receipt of the certified copy of the priority document filed on August 27, 2003 or an acceptance of the drawings filed on August 27, 2003. Accordingly, Applicants respectfully request that the Examiner indicate receipt of the certified copy of the priority document and acceptance of the drawings in the next Action.

**II. Statement of Substance of Interview**

Applicants thank the Examiner for having an interview with Applicants' representative on August 17, 2009. An Examiner's Interview Summary Record (PTO-413) was attached forwarded on August 20, 2009.

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: None
2. Identification of claims discussed: Claim 1
3. Identification of art discussed: None
4. Identification of principal proposed amendments: None
5. Brief Identification of principal arguments: None
6. Indication of other pertinent matters discussed: Applicants' representative and the Examiner discussed the Declaration filed on June 5, 2009.
7. Results of Interview: The Examiner stated that the Declaration was not considered because it was not properly executed.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

### **III. Present Claims Comply with 35 U.S.C. § 112, first paragraph**

1, 5, 6 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner asserts that the figures, Tables and description provided by the instant specification are entirely drawn to the inclusion of nifedipine in the claimed sustained-release composition. In particular, the Examiner asserts that there is no description provided in the specification for isradipine, lovastatin and glypizide, as required by instant claim 10, or, for the plethora of drugs that are encompassed in the language of claim 1.

Solely to expedite the prosecution, Applicants have amended independent claims 1 and 10 to recite only nifedipine and lovastatin in the claimed sustained-release composition.

While admitting that the original specification has sufficient written description for the inclusion of nifedipine in the claimed sustained-release composition, the Examiner asserts that there is no description provided in the specification for lovastatin. Page 2, Office Action of August 20, 2009.

Applicants respectfully disagree. Specifically, Example 4 as shown in Table 1 in the original specification clearly discloses that a formulation comprising lovastatin exhibits zero order kinetics over a period of 24 hour. *See* Page 9 and Figure 2. Accordingly, from reading the original specification, one of ordinary skill in the art would understand that a formulation comprising any of the drugs, nifedipine and lovastatin, as recited in present claims is expected to exhibit the same kinetics.

For the reasons set forth above, Applicants respectfully request that this rejection under 35 U.S.C. § 112 be reconsidered and withdrawn.

#### **IV. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.116  
Application No.: 10/650,931

Attorney Docket No.: Q110631

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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CUSTOMER NUMBER

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